

1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE COMPANY

1.1 PRODUCT IDENTIFIER

PRODUCT NAME:

Serazym® Ovalbumin (Incubation at 37 °C, 7 standards)
Serazym® Ovalbumin (Incubation at 20...25 °C, 6 standards)

CATALOG NUMBER:

E-041a-1
E-041c-1

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

In vitro tests

Enzyme immunoassays for quantitative determination of ovalbumin in biological fluids
Relevant identified use PROC15: Laboratory chemical
Reserved for industrial and professional use.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Seramun Diagnostica GmbH
Spreenhagener Straße 1
15754 Heidesee
GERMANY

Phone: +49 33767-791 10
Fax: +49 33767-791 99
E-mail: info@seramun.com

1.4 EMERGENCY TELEPHONE NUMBER

Phone: +49 33767-791-10 Available only during office hours.

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

The HRP-conjugate stabilizer and TMB-substrate solution used in the products are classified as toxic for reproduction (Repr. 1B, H360D) according to EU regulation (EC) 1272/2008, modified by (EC) 2016/1179.

The Standards and Control solution used in the products are classified as sensitising to skin (Skin Sens. 1, H317) according to EU regulation (EC) 1272/2008.

The preservatives are generally toxic to aquatic organisms.

2.2 LABEL ELEMENTS

Applicable for the components **Standards** and **Control**:



Pictogram

Signal word

Hazard class(es)

Hazard statement(s)

Precautionary statement(s)

EUH statement

Warning!

Skin sensitization, Skin Sens. 1

H317: May cause an allergic skin reaction.

P280: Wear protective gloves/ protective clothing/ eye protection/ face protection.

EUH208: Contains 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

Applicable for the component **HRP-conjugate**:



Pictogram
Signal word: Danger!
Hazard class(es): Reproductive toxicity (Repr. 1B)
Hazard statement(s): H360D: May damage the unborn child.
Precautionary statement(s): P280: Wear protective gloves/ protective clothing/ eye protection/ face protection.
P308+P313: If exposed or concerned: Get medical advice/attention.

Applicable for the component **TMB-substrate**:



Pictogram
Signal word: Danger!
Hazard class(es): Reproductive toxicity (Repr. 1B)
Hazard statement(s): H360D: May damage the unborn child.
H335: May cause respiratory irritation.
H319: Causes serious eye irritation.
H315: Causes skin irritation.
Precautionary statement(s): P280: Wear protective gloves/ protective clothing/ eye protection/ face protection.
P308+P313: If exposed or concerned: Get medical advice/attention.

2.3 OTHER HAZARDS

Chemicals bear specific risks in general. That is why these are handled by qualified staff only in compliance with health and safety regulations.

None of the components are listed as PBT or vPvB relevant.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

All products are mixtures.

3.2 MIXTURES

Wash buffer: TRIS buffer with inorganic salts and preservative thimerosal (0.01%)
Concentrations of dangerous components according to (EC) 1272/2008 are below the concentration limits mentioned in the law.

Sample diluent: TRIS buffer with inorganic salts, bovine serum albumin (BSA) and preservative thimerosal (0.02%)
The bovine serum albumin (BSA) was collected at a USDA licensed company.
Concentrations of dangerous components according to (EC) 1272/2008 are below the concentration limits mentioned in the law.


Safety data sheet
according to (EC) 1907/2006, article 31

Enzyme Immunoassays
Serazym® Ovalbumin (ELISA)

File: SDBR_E-041_Ovalbumin_E_v01.docx
Version: 01
Last version: 08 (SDBR_E_ELISA-01)
Date: 2017-12-07
Revision: 2018-11-14
Valid from: 2018-11-23
Page: 3 of 10


Standards, Control: TRIS buffer with inorganic salts, bovine serum albumin (BSA), assay specific antigen and as preservative a mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
The bovine serum albumin (BSA) was collected at a USDA licensed company.

Dangerous components according to (EC) 1272/2008:

REACH Register-number	EINECS	CAS-No.	name	percentage	symbol	H-statements
Not available	613-167-00-5	55965-84-9	Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	0.015	 Danger!	H302, H314, H317, H410


HRP-conjugate: TRIS buffer with inorganic salts, bovine serum albumin (BSA), as active substances IgG (rabbit) and horseradish peroxidase (EC1.11.1.7) and as preservative a mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
The bovine serum albumin (BSA) was collected at a USDA licensed company.

Dangerous components according to (EC) 1272/2008:

REACH Register-number	EINECS	CAS-No.	name	percentage	symbol	H-statements
01-2119472430-46-XXXX	212-828-1	872-50-4	N-Methyl-2-pyrrolidone	< 2.0	 Danger!	H315, H319, H360D, H335


TMB-substrate: Aqueous solution of 3,3',5,5'-Tetramethylbenzidine (TMB), hydrogen peroxide, containing citrate and as preservative a mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Dangerous components according to (EC) 1272/2008:

REACH Register-number	EINECS	CAS-No.	name	percentage	symbol	H-statements
01-2119472430-46-XXXX	212-828-1	872-50-4	N-Methyl-2-pyrrolidone	15	 Danger!	H315, H319, H360D, H335

Stop solution: Diluted sulphuric acid (0.25 M)

Dangerous components according to (EC) 1272/2008:

REACH Register-number	EINECS	CAS-No.	name	percentage	symbol	H-statements
01-2119458838-20-XXXX	231-639-5	7664-93-9	Sulphuric acid	2.5	 Warning!	H290, H314

For the full text of all H-statements, see section 16.

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move the concerned person into fresh air. In case of apnoea, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with plenty of water. Consult a physician.

In case of eye contact

Rinse the opened eye for several minutes with running water, if necessary remove contact lenses. Consult an ophthalmologist.

If swallowed

Never give anything by mouth to an unconscious person.
Rinse mouth with water, drink in maximum two drinking glasses water, consult a physician.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

No data available.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available.

5. FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media

Use water spray, alcohol resistant foam, solid extinguishing agent or carbon dioxide.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

The components of the product itself are not inflammable; extinguishing measures should therefore be prepared for an environmental fire.

In case of fire toxic vapors, e.g. nitric oxide and carbon monoxide, can be released.

5.3 ADVICE FOR FIREFIGHTERS

Wear breath protective mask and protective clothes if necessary during firefighting.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Use personal protective equipment. Avoid breathing vapor/mist/gas. Care for appropriate ventilation.

6.2 ENVIRONMENTAL PRECAUTIONS

Keep away from drains. Avoid contamination of water or soil.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Adsorb with inert absorbance material and dispose as hazardous waste. Keep in a suitable, closed container.

6.4 REFERENCE TO OTHER SECTIONS

For personal protection, see section 8
For disposal considerations, see section 13

7. HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

No smoking, eating, drinking, chewing gum or storage of food or beverages in the working laboratories.
Wash hands after work. Remove safety clothing before entering a break room.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store tightly closed at a cool, dry place. Seal opened bottles carefully and store them in an upright position.

Recommended storage temperature: 2-8°C

Storage classification: 12 (nonflammable liquids)
segregate from: class 1 (explosives)
class 4.1A (flammable solids)
class 4.3 (dangerous when wet)
class 6.2 (infectious)
class 7 (radioactive)

Further information:
Store separated from foodstuffs.
Protect from unauthorized access.

7.3 SPECIFIC END USE(S)

Use only in accordance to the instructions for use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

EINECS	name	limit value according to MAK (TRGS 900)	limit value according to BGW (TRGS 903)
212-828-1	N-Methyl-2-pyrrolidone	82 mg/m ³	150 mg/l urine at the end of a shift, parameter: 5-Hydroxy-N-Methyl-2-pyrrolidone

If the products are used according to the instructions, no air pollution is to be expected.

8.2 EXPOSURE CONTROLS

Consider the usual good hygiene and safety practice by handling chemicals.
Pregnant women should strictly avoid inhalation or skin contact.

Personal protective equipment

Eye/face protection: safety glasses with side shields conforming to EN 166 (EC), NIOSH (US)

Skin protection: protective gloves of nitril rubber (thickness min. 0.28 mm, AQL1,5) or nature latex (thickness min. 0.22 mm, AQL 1,5), satisfying the norm EN 374

Body protection: impermeable protective clothing, the kind of protective equipment has to be selected depending from concentration and amount of dangerous substance at the specific workplace.

Respiratory protection: not required, if handled according to the intended use. In case of a divergent risk assessment use a full-face respirator with multi-purpose combination respirator cartridge Type ABEK (EN 14387).

Environmental exposure controls: keep away from drains, water or soil.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

component	description	colour	odour
Wash buffer	liquid product	colourless	odourless
Sample diluent	liquid product	pink	odourless
HRP-conjugate	liquid product	green	odourless
Standards, Control	liquid product	pink	odourless
TMB-substrate	liquid product	colourless	characteristic
Stop solution	liquid product	colourless	odourless

component	pH value	boiling point	flash point	explosive properties
Wash buffer	7.3 – 7.5	101 °C	not applicable	none
Sample diluent	7.3 – 7.5	102 °C	not applicable	none
HRP-conjugate	7.3 – 7.5	102 °C	not applicable	none
Standards, Control	7.3 – 7.5	102 °C	not applicable	none
TMB-substrate	4.3 – 4.5	102 °C	not applicable	none
Stop solution	1	103 °C	not applicable	none

component	oxidising properties	vapour pressure	relative density
Wash buffer	none	not measured	1.11 g/ml
Sample diluent	none	not measured	1.0026 g/ml
HRP-conjugate	none	not measured	1.043 g/ml
Standards, Control	none	not measured	1.0026 – 1.007 g/ml
TMB-substrate	none	not measured	1.013 g/ml
Stop solution	none	not measured	1.02 g/ml

component	solubility	water solubility	viscosity
Wash buffer	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Sample diluent	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
HRP-conjugate	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Standards, Control	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
TMB-substrate	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured
Stop solution	complete soluble/miscible in protic solvents	complete soluble/miscible	not measured

9.2 OTHER INFORMATION

No further dangerous properties known.

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

No data available.

10.2 CHEMICAL STABILITY

Store at 2 – 8°C

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

If the products are used according to the instructions for use, no hazardous reactions are to be expected.

10.4 CONDITIONS TO AVOID

Light, heat, moisture (This will not cause a dangerous reaction, but could destroy the quality of the products).

See storage conditions, section 7.2

10.5 INCOMPATIBLE MATERIALS

Oxidizing agents, metals (This will not cause a dangerous reaction, but could destroy the quality of the products). The stop solution may be corrosive to metals.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Dangerous decomposition products are not known.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

(a) Acute toxicity

component	valuation	value	species
N-Methyl-2-pyrrolidone	LD ₅₀ (oral)	3,598 mg/kg	rat
	LC ₅₀ (inhalativ)	>5.1 mg/l	rat
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	LD ₅₀ (oral)	2,630 mg/kg	rat
	LC ₅₀ (inhalativ)	>5.0 mg/l	rat

(b) Skin corrosion/irritation

component	valuation	value	species
N-Methyl-2-pyrrolidone	LD ₅₀ (dermal)	8,000 mg/kg	rabbit

Risk of skin resorption (HRP-conjugate and TMB-substrate).

May cause an allergic skin reaction (standards and controls).

(c) Serious eye damage/irritation
Irritation effect (stop solution).

(d) Respiratory or skin sensitization
No information available.

(e) Germ cell mutagenicity
No information available.

(f) Carcinogenicity
No information available.

(g) Reproductive toxicity
For conjugate and TMB-substrate: May damage the unborn child: N-Methyl-2-pyrrolidone (Repr. 1B)

(h) STOT-single exposure
For HRP-conjugate and TMB-substrate: May cause respiratory irritation.
Other components: No specific target organ toxicant, because no component is known as specific target organ toxicant.

(i) STOT-repeated exposure
No specific target organ toxicant, repeated exposure.

(j) Aspiration hazard
No information available.

11.2 FURTHER TOXICOLOGICAL INFORMATION

Quantitative data on the toxicity of the mixtures are not available.

Calculation of ATE according to (EC) 1272/2008, Appendix I: see section 15.1

Hazardous properties cannot be excluded but are unlikely when the products are handled appropriately.

Further data: Handle in accordance with good industrial hygiene and safety practice.

12. ECOLOGICAL INFORMATION

12.1 TOXICITY

N-Methyl-2-pyrrolidone:

species	valuation	value
bluegill (<i>Lepomis macrochirus</i>)	LC ₅₀ (mg/l/96h)	832
gold orfe (<i>Leuciscus idus</i>)	LC ₅₀ (mg/l/96h)	> 500
green alga (<i>Desmodesmus subspicatus</i>)	IC ₅₀ (mg/l/72h)	> 500
invertebrates (<i>Daphnia magna</i>)	EC ₅₀ (mg/l/48h)	4897

Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

species	valuation	value
rainbow trout	LC ₅₀ (mg/l/96h)	0.19
green alga	IC ₅₀ (mg/l/72h)	0.027
invertebrates (<i>Daphnia magna</i>)	EC ₅₀ (mg/l/48h)	0.16

12.2 PERSISTENCE AND DEGRADABILITY

Biological degradability:

substance	value	evaluation
N-Methyl-2-pyrrolidone	> 90%/20d	easily biologically degradable
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	< 50%/10d	not easily biodegradable

12.3 BIOACCUMULATIVE POTENTIAL

Distribution: log P(o/w): ≤ 4 (for N-Methyl-2-pyrrolidone), there is no bioaccumulation expected.
log P(o/w): = 0,401 (for mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)), there is no bioaccumulation expected

12.4 MOBILITY IN SOIL

No data available.

12.5 RESULTS OF PBT AND vPvB ASSESSMENT

None of the components is listed as PBT or vPvB relevant.

12.6 OTHER ADVERSE EFFECTS

Herbicide and nematicide effects known.

Keep away from drains. Avoid contamination of water or soil.

If used appropriately, no ecological problems are to be expected.

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Products:

Disposal should be made in accordance with national and local regulations and laws.

Packaging:

Emptied packaging can be given to local recycling or waste disposal.

14. TRANSPORT INFORMATION

The following classification is due to the stop solution

14.1 UN NUMBER

ADR/RID: UN 3264

IMDG: UN 3264

IATA: UN 3264

14.2 UN PROPER SHIPPING NAME

ADR/RID: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULPHURIC ACID SOLUTION)

IMDG: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULPHURIC ACID SOLUTION)

IATA: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (SULPHURIC ACID SOLUTION)

14.3 TRANSPORT HAZARD CLASS(ES)

ADR/RID: 8

IMDG: 8

IATA: 8

14.4 PACKING GROUP

ADR/RID: III

IMDG: III

IATA: III

14.5 ENVIRONMENTAL HAZARDS

ADR/RID: No

IMDG: Marine pollutant no

IATA: No

14.6 SPECIAL PRECAUTIONS FOR USER

ADR/RID: tunnel restriction code E

IMDG: EmS-numbers: F-A, S-B

IATA: no

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL73/78 AND THE IBC CODE

These products will be shipped only in approved card boxes.

Reference:

ADR: limited quantities LQ: 5 L
excepted quantities EQ Code E1
maximum net quantity per inner packaging: 30 ml
maximum net quantity per outer packaging: 1000 ml

IMDG: limited quantities LQ 5 L
excepted quantities EQ Code E1
maximum net quantity per inner packaging: 30 ml
maximum net quantity per outer packaging: 1000 ml

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

This safety data sheet meets the requirements of the regulation (EC) 453/2010 to amending regulation (EC) 1907/2006 and (EC) 2016/1179 modifying (EC) 1272/2008.

The calculated toxicity (ATE) of the mixtures according (EC) 1272/2008, Annex I:

Wash buffer	19,000	mg/kg body weight	no classification
Sample diluent	199,000	mg/kg body weight	no classification
Standards, Control	190,000	mg/kg body weight	no classification
HRP-conjugate	248,000	mg/kg body weight	no classification
TMB-substrate	25,300	mg/kg body weight	no classification
Stop solution	85,600	mg/kg body weight	no classification

According (EC) 1272/2008, Annex I: no classification not hazardous to water.

Calculated L(E)C₅₀ of the mixtures:

Wash buffer	4,720	mg/l	no classification (> 100 mg/l)
Sample diluent	21,600	mg/l	no classification (> 100 mg/l)
Standards, Control	520	mg/l	no classification (> 100 mg/l)
HRP-conjugate	570	mg/l	no classification (> 100 mg/l)
TMB-substrate	5,570	mg/l	no classification (> 100 mg/l)
Stop solution	1,160	mg/l	no classification (> 100 mg/l)

Water endangering class according to VwVwS (Germany): Water endangering class 1

Employment limitations:

Reference is made to the restrictions of employment specified in the Youth Employment Act and the Maternity Protection Act.

Other regulations, limitations and prohibitive regulations:

Substance of very high concern (SVHC) according (EC) 1907/2006 (REACH), Article 57:

N-Methyl-2-pyrrolidone (CAS-No. 872-50-4)

15.2 CHEMICAL SAFETY ASSESSMENT

No data available.

16. OTHER INFORMATION

Full text to the H-statements mentioned in section 3:

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.
H410	Very toxic to aquatic life with long lasting effects.

Categories of the acute toxicity (ATE) according to (EC) 1272/2008:

Category 1	0 < ATE ≤ 5	(oral in mg/kg body weight)
Category 2	5 < ATE ≤ 50	(oral in mg/kg body weight)
Category 3	50 < ATE ≤ 300	(oral in mg/kg body weight)
Category 4	300 < ATE ≤ 2.000	(oral in mg/kg body weight)

Categories of the acute/chronic aquatic toxicity according to (EC) 1272/2008:

Category 1	L(E)C ₅₀ ≤ 1 mg/l
Category 2	1 < L(E)C ₅₀ ≤ 10 mg/l
Category 3	10 < L(E)C ₅₀ ≤ 100 mg/l
Category 4	slightly soluble substances

Further information:

The information stated above is based on our actual knowledge and is intended to describe our products concerning safety recommendations. The information does not assure product properties and is therefore no basis for legal action.

Changes with respect to the previous version:

- Generation of a separated safety data sheet for both products E-041a-1 and E-041c-1 due to changed product classification and resulting labelling requirements
- General updates in section 1
- Amendments in sections 2, 3 and 15, due to regulation (EC) 2016/1179 modifying (EC) 1272/2008, new calculation of the toxicity using actual data in section 15